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Award Number: W81XWH-06-2-0031

TITLE: Diabetes Care and Treatment Project: A Diabetes institute of the Walter Reed Health Care System and Joslin Telemedicine Initiative

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REPORT DATE: September 2010

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

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REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-09-2010		2. REPORT TYPE Final		3. DATES COVERED (From - To) 10 MAR 2009 - 9 AUG 2010	
4. TITLE AND SUBTITLE Diabetes Care and Treatment Project: A Diabetes institute of the Walter Reed Health Care System and Joslin Telemedicine Initiative				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-06-2-0031	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. Robert A.Vigersky E-Mail: robert.vigersky@amedd.army.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) T. R. U. E. Research Foundation San Antonio, TX 78217				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients the care process, that empowers the patient to better manage their disease, that can be performed a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research was to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. The need for diabetes disease management is driven by the knowledge that diabetes is not currently curable, but it is treatable, and its complications are preventable. The primary goal of treatment is to enable people with diabetes to live healthy lives.					
15. SUBJECT TERMS Joslin Vision Network, telemedicine, diabetes mellitus, diabetic retinopathy, comprehensive diabetes management, diabetes case management, diabetes behavioral assessment tool					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)
			UU	42	

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Introduction

Diabetes Mellitus (DM) is a prevalent costly condition that causes significant morbidity and mortality. In the United States nearly 24 million people or 7.8% of the total population have diabetes and of whom at least 5.7 million are undiagnosed. An additional 54 million people are estimated to have pre-diabetes. Diabetes has recently been identified as the fifth leading cause of death in the United States (2). Consistent with devastating personal effects of diabetes, the costs to the health care system were estimated at \$174 billion in 2007 (\$116 billion in direct medical costs and \$58 billion in reduced national productivity (1). People with diagnosed diabetes, incur average expenditures of \$11,744 per year, of which \$6,649 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures that are more than twice the amount of expenditures in the absence of diabetes (<http://diabetes.niddk.nih.gov/DM/PUBS/statistics/>). There is abundant evidence and documentation that diabetes is a major component of all health care expenditures in the United States with most of this cost associated with long term complications of diabetes specifically, retinopathy, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease resulting in amputations (. Furthermore, the actual national burden of diabetes is likely to exceed the \$174 billion estimate because it omits the social cost of intangibles such as pain and suffering, care provided by nonpaid caregivers, and excess medical costs associated with undiagnosed diabetes.

Traditional health care delivery systems involve individual providers reacting to patient-initiated complaints and visits. Care is often fragmented, disorganized, duplicative, and focused on managing established diseases and complications. Management of the disease is provider directed and focuses on pharmacologic and technologic interventions with little attention to patient self-management behaviors and provider-patient interactions (6). Evidence shows that improving care for diabetic patients results in cost savings for health care organizations and recent economic analysis studies have shown that diabetes eye care and preconception care were found to be cost saving as was preventing neuropathy and improving glycemic control.

Despite advances in treating these complications, efforts aimed at prevention are the best approach to reduce morbidity and mortality. In the last decade, innovative interventions for health care delivery have emerged that show promise for improving care, outcomes and costs for individuals and populations with diabetes. Disease and case management are two interventions that continue to demonstrate considerable potential and promise. In the arena of prevention, objectives 5-11 through 5-15 of the *Healthy People 2010* for the United States directly relate to improving screening for complications involving the retina, the kidney, the extremities, the oral cavity and the monitoring of glycemic control.

Two problems to overcome in order to reduce or prevent diabetic complications are (1) providing access of all diabetic patients to proven diagnostic and treatment strategies which reduce the risk of vision loss and (2) identifying effective methods to improve the metabolic control of patients with diabetes to reduce the risk of chronic complications. The challenge to overcome these problems is formidable. For example, intensive research over the last 30 years has developed methods that virtually eliminate diabetic retinopathy as a cause of severe vision loss. Nevertheless, diabetes remains the leading cause of new blindness in working-aged adults in the United States (1). The reason for this incongruity is many patients do not receive quality eye care because of geographical barriers, insufficient health insurance or financial

resources, or patient or health care provider ignorance.

In a review article aimed at examining the effectiveness of disease management and case or care management for people with diabetes, the authors found that disease and care management was effective as interventions when delivered concurrently and also when delivered in conjunction with educational interventions, decision support and reminders on performance issues, such as, timely retinal evaluation. These authors went on to indicate that one of the most pressing needs is to better define effective interventions as disease management has multiple component interventions. It may be that for the optimal use of resources only the interventions that contribute the most to positive outcomes need to be implemented. These interventions have yet to be defined. Additional research will need to be done, however, to identify the optimal intensity and frequency of these interventions as well as a consideration of whether professionals other than nurses (social workers, health aids or pharmacists) can function as care managers. Other research areas of importance were identified as: consideration of integration of disease management into existing health care systems, the effect of disease and care management on long-term health and quality of life outcomes, such as, cardiovascular disease events, visual impairment, amputations, renal failure and mortality, and the effect of care management on blood pressure, weight, lipid levels and provider screening rates for retinopathy, peripheral neuropathy and microalbuminuria. Finally this review was unable to identify any appropriately rigorous studies aimed at evaluating the cost effectiveness of the care management intervention.

Overview

This annual report for the ongoing JVN Telehealth program at WRAMC provides an overview and status report of the studies designed to address the research questions posed above. This telehealth initiative is a unique opportunity to leverage the technological developments achieved over the past 5 years in the development of the JVN eye care and disease management programs to provide evaluations of the multiple diabetes disease management interventions from a single unified platform, the JVN Comprehensive Diabetes Management Program. The implementation of the JVN programs is extraordinarily timely in light of a recent publication in the Journal of the American Medical Association promoting the use of organized care management processes to improve the health care quality for patients with chronic diseases. The authors conclude that, although the use of care management processes vary greatly among physician organizations, the usage is low on average. They call on government and private purchasers of health care to increase the usage of care management processes through provision of external incentives for improvement of health care quality and to promote and assist physician organization to increase or improve their information technology capabilities. This continuation proposal is positioned to allow participants to play a lead role in developing evidence from rigorous multi-center studies to further support these recommendations.

The research proposals described below will leverage the successful deployment of the Joslin Vision Network (JVN) Eye Health Care program and the integration of the Comprehensive Diabetes Management Program (CDMP) to provide continuum of care for diabetic patients. The CDMP application has been developed under this collaboration and represents participation and input from leading experts in diabetes care from the Joslin Diabetes Center, Department of Defense, and the Veterans Health Administration.

Various studies have been deemed critical in order to provide the medical evidence to support preliminary data and expectations that this program will provide significant reductions in health care dollar expenses while

maintaining a high quality of care as assessed through a reduction in complications such as blindness from diabetes. The expectation is that the use of this program will also increase the access of patients to appropriate care and provide a very powerful tool that will empower the patient to improve their own management of their diabetes.

The studies proposed in this continuing proposal are prospective in nature and involve multiple participating centers. There are 8 different research projects associated with the Joslin/University of Hawaii research program (as distinct from the research related to the development of new CDMP functionality) taking place across 4 sites. As shown in the table below, four of these research projects are taking place at Walter Reed. The study designs across the four Walter Reed projects vary from each other. Two are observational studies (those designed to assess the test-retest reliability of the BAT), one is a randomized clinical trial that will provide prospective data for insertion into decision models (the JVN cost efficiency study), and one is pre-/post- usability test of the implementation of the CDMP in the Diabetes Institute at Walter Reed (CDMP usability/workflow study). The specifics of the study designs are described in the attached Statements of Work.

User evaluations of the Study Manager Module are not a scientific aim and therefore do not have a study associated with them. Rather, Walter Reed has been using the Study Manager Module more than any other site, for the projects enumerated here as well as others, and we have been refining it as we gain experience with this tool.

The activity and progress that occurred during this PoP is highlighted in yellow.

Research Studies by Site

Project	Site				Status
	Joslin	Hawaii	WRAMC	VA	
Prospective cost efficiency study performed using the Telehealth Eye Care Module			√		Recruitment completed, data completion anticipated 30 June 2010
Prospective risk benefit study using the Telehealth Eye Care Module				√	Recruitment ongoing
CDMP usability and impact on clinical workflow study			√		Data collection and analyses completed
An Assessment of the Test-Retest Reliability of the CDMP BAT	√	√	√		Data collection complete at Joslin, VA, WRAMC. HI has ceased data collection due to lack of funds. Combined analyses of Joslin and WRAMC data was conducted at WRAMC. Data analysis demonstrated

					poor correlation between activity and food ($r = 0.4$). Manuscript combining the BAT reliability and validity studies is in progress.
An Assessment of the Validity of the CDMP BAT	√	√	√		Recruitment completed at WRAMC and was discontinued at HI, therefore only subjects enrolled at WRAMC were included in predictive validity. Activity and food logs coded by HI; all data analyzed by WRAMC. Manuscript combining the findings of the BAT reliability and validity studies is in progress.
Additional Human Factors Study for the CDMP Application: Expert Review of the CDMP	NA	NA	NA	NA	Completed; suggested changes to CDMP incorporated and are being used to further refine and develop CDMP as a tool to enhance case managers and primary care providers' management of patients with diabetes.

Notes: NA means not applicable. The Expert Review of the CDMP did not require recruiting subjects and was done by employees of the American Institutes for Research at their offices.

Statement of Work and Key Research Accomplishments

The different studies and progress since FY06 are enumerated below:

1. Prospective multi-center cost efficiency study performed using the JVN Telehealth Eye care module

DESCRIPTION:

The primary questions are: What are the costs associated with diabetic retinopathy evaluations performed by an ophthalmologist or optometrist with a dilated eye examination and the JVN system using digital video imaging through an undilated pupil? What is the cost-effectiveness of ophthalmoscopy performed by eye care professionals compared to the Joslin Vision Network?

Specifically, the purpose of this study is to compare the costs and cost-effectiveness of the Telehealth Eye Care module with conventional clinic-based eye examinations among a diabetic cohort receiving annual eye examinations. Consenting patients (n = 360) at sites of the Walter Reed Army Health Care System (WRHCS) with type 1 or type 2 diabetes mellitus and scheduled for eye examinations on an annual basis were enrolled in the study and randomized to conventional clinic-based eye examinations or eye examinations performed by the Telehealth Eye Care Module (plus an assessment of visual acuity). Subjects were followed for one year. The study will track all costs that accrue over that year in the provision of care for both modalities, including labor, equipment, travel for the study subjects, and lost wages/productivity for study subjects, among others. Cost-effectiveness will be measured based on study subjects' compliance with the clinical eye examination and follow-up recommendations and diagnostic and treatment outcomes. We will *a priori* generate cost-effectiveness data based on diagnoses of diabetic retinopathy and macular edema. In a cost consequence analysis, we will consider other diagnostic outcomes and outcomes in aggregate. Additionally, we will impute cases of expected vision loss and, therefore, project differences in the number of cases of vision loss averted between modalities.

PROGRESS:

The enrollment goal was achieved in June 2009. Data collection will continue until the last subject has either completed the study.

MILESTONES AND DELIVERABLES:

Completion of data collection is expected in summer of 2010 and completion of initial data analyses for presentation at an annual meeting in 2011 (TBD). Ultimately we hope to publish our findings and deploy the JVN telehealth eye care module throughout military treatment facilities (MTFs) in the United States.

Toward this end and building on the clinical effectiveness of this program, we applied for and have been awarded funding through the NARMC initiative, Advances in Medical Practice (AMP), to deploy retinal image acquisition workstations (IAWs) to primary care clinics in 10 MTFs throughout NARMC. We expect to begin this program in the fall of 2010. If this program is successful it is likely that retinal IAWs will be deployed throughout military treatment facilities (MTFs) and civilian clinics in the United States and abroad, thus providing an effective and economic means of screening retinal eye disease in medically underserved areas.

2. The Usability and Workflow Impact on Diabetes Care Specialists of the Comprehensive Diabetes Management Program (CDMP).

DESCRIPTION:

This project examined the usability and impact on clinical workflow of the Comprehensive Diabetes Management Program (CDMP). The CDMP is an, interactive, web-based tool for physicians, care managers and people with diabetes. The project examined the CDMP's usability and impact on clinical workflow by comparing them to those of the existing, baseline health information system in the Walter Reed Army Health Care System (WRHCS). Specifically, we examined the Diabetes HealthCard data (which documents the process and quality measures of the Diabetes Quality Improvement Program (DQIP)) of selected diabetes health care providers and administered several different questionnaires regarding the usability of the diabetes care system before and after adoption of the CDMP.

We also conducted structured focus group discussions with the providers lead by a trained, experienced facilitator. Health care providers selected for this study were the Nurse Practitioners (NPs) of the Diabetes Institute of the Walter Reed Health Care System (not just Walter Reed Army Medical Center). All of the recruiting, data collection, and data analyses were done through a contract with the American Institutes for Research so as to minimize coercion of the study participants and maintain objectivity.

PROGRESS:

The findings of the study and a structured focus group with the DI nurse practitioners **demonstrated that the program was visually appealing and overall had appropriate content, but needed improvement in navigation and terminology. A theme that occurred throughout both focus groups was that CDMP is a tool for managing diabetes from a generalist or case manager perspective versus a specialized diabetes practitioner.**

MILESTONES AND DELIVERABLES:

As this is just one component of a multi-factored and ongoing project, the findings are being used to further refine and develop CDMP as a tool to enhance case managers and primary care providers' management of patients with diabetes.

3 and 4. Clinical Validation of the Behavior Assessment Tool (BAT) developed for the CDMP application (including test-retest reliability and validity).

The Behavioral Assessment Tool (BAT) was developed as a stand-alone module within the CDMP. It is a screening questionnaire containing questions about psycho-social factors, nutrition, physical activity, alcohol and tobacco use, medications, general health, self-monitoring of blood glucose and economic factors. There are two studies associated with testing its reliability and validity. An Assessment of the Test-Retest Reliability of the CDMP BAT and An Assessment of the Validity of the CDMP BAT.

DESCRIPTION:

The reliability assessment was a multi-site observational study with two measurements per study subject taking place 2 to 4 weeks apart. The original sites were: the VA Boston Healthcare System (n = 42), Joslin Diabetes Center (n = 43 - with the additional subject being approved by the IRBs), Walter Reed Army Medical Center (n = 42), and community health centers in Hawaii (n = 42), however, due to unexpected challenges in recruitment at the community health centers, recruitment was discontinued in Hawaii. The studies are explained in detail in the Annual Report dated 30 April 2009.

PROGRESS:

The VA, Joslin, and Walter Reed have completed all data collection. Poster presentations of the studies were presented at the CDC Diabetes Translation Conference in, Atlanta, April - May 2007.

MILESTONES AND DELIVERABLES:

A publication describing the implementations, findings and recommendations of the BAT reliability and validity studies is in preparation.

PROGRESS:

Data collection for this study is complete at Joslin and at WRAMC. Joslin enrolled 72 subjects: 63 completed the study and 9 either dropped out or were lost to follow-up. WRAMC enrolled 75, 62 subjects completed the study.

Similar to the BAT reliability study, recruitment was discontinued in Hawaii as a result of unexpected challenges in recruitment at the community health centers. Investigators at University of Hawaii coded the activity and food logs for data analysis.

MILESTONE AND DELIVERABLES:

Analyses of the data has been completed.

Findings from the Test-retest Data Analyses

We calculated the correlation (i.e., Cronbach alpha, or α) between the two administrations of the BAT, item-by-item, using the combined data from all sites, as well as kappa coefficients as needed. When necessary, such as when there was no variance in either or both the BAT1/BAT2 questions, we calculated kappa coefficients to measure the amount of agreement between administrations. The item test-retest correlations for the combined data range from 0.47 to 0.99. By site, item test-retest correlations ranged from 0.16 to 1.0. The number of items that are below the standard threshold of $\alpha=0.70$ for the VA Boston Endocrinology Clinic, the Joslin Diabetes Center, and Walter Reed Army Medical Center are 14/39, 4/39, and 5/39 respectively. The number of items for which we could not calculate α is 0, 3, and 4 respectively; for these items we calculated kappa coefficients, which were generally 1.0, indicating perfect agreement. The items with the lowest correlations or agreement are those pertaining to dietary habits over the last 2 weeks, physical activity, and taking medications.

Findings from the Validation Data Analyses

We calculated the correlation (Pearson, Spearman, of Kendall tau, as appropriate) between study subjects' responses to each specific BAT question and similar "criterion measures" from other surveys and tests. We then replicated the analyses for each site individually.

The correlations between the BAT items and the criterion measures are generally in the range of 0.30 to 0.60. The items in the 0.30 range tend to be about taking medications and dietary habits. These correlations are consistent across sites. According to Nunnally (p. 1978), it is reasonable to expect only modest correlations between a criterion and either an individual predictor test or a combination of predictor tests. The reason for this is that people and the situations in which the tests are administered are complex. This complexity serves to reduce the correlation. A validity correlation coefficient of above 0.35 is considered "very beneficial". According to Cohen (1988), a correlation between 0.5-0.3 is moderate, which again is sufficient for the purposes of this study. Therefore, many of the correlations indicate reasonable validity for the BAT questions.

However, as is often the case in instrument development, we may revise some items for future versions of the BAT so as to improve consistency across administrations and across sites and to increase validity.

5. Deployment of JVN Telehealth CDMF application into the Department of Defense HealtheForces. Robert Vigersky MD, and Sven-Erik Bursell PhD.

PROGRESS:

Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005. Diabetes Institute staff at WRAMC received CDMP training in June 2005. The Diabetes Institute staff is currently developing the process and procedures for use of the CDMP in their clinic and the Usability/Workflow Study has been completed and findings are being used to further refine CDMP as a case management tool (see #2 above). Recent requirements regarding interfacing to CHCSII are currently being investigated. A three-stage plan for integration which was initiated after discussions with representatives of the Office of the Surgeon General of the Army is being modified to be consistent with the Common Development Environment (CDE) being developed by TATRC as a platform for the integration of clinical programs such as CDMP into AHLTA.

Project Deviations

Reports in previous fiscal years identified CDMP and related telehealth studies that were being conducted at consortium members' facilities. This report specifically provides an overview of the studies and their progress being conducted at WRAMC. Description of the accomplishments and problems encountered to data collection and/or analyses are identified under the section for each study.

Implementation of Study Manager

Study Manager is currently being used to manage and monitor the progress of three studies being conducted under the direction of COL Vigersky. The primary objective of each study is: 1) Measure the impact of a real-time continuous glucose monitoring (CGM) device on patients with Type 2 diabetes; 2) Determine the impact of a video cell phone reminder system on glycemic control in patients with diabetes mellitus; 3) Determine the impact of a bedside broadband videodevice reminder system on glycemic control in older adults with diabetes mellitus living independently at the Armed Forces Retirement Home. Study manager was also used to manage the data collected for the Genetic Screening in Diabetes study. The purpose of the Genetic Screening study, which is not closed to enrollment was to obtain blood for genetic analysis from patients with diabetes mellitus complicated by nephropathy, autonomic neuropathy, or retinopathy and from their parents and/or siblings in order to determine if any or all of these complications are linked to one or more of the proposed candidate genes.

Study manager will be implemented with additional studies. The diversity of the studies as well as the diversity of personnel managing the studies provides an informal, but comprehensive platform from which to measure the usability and impact of study manager on workflow (efficiency) and effectiveness of data collection. Additionally, in September, 2008, the "architects" of study manager (Sven Bursell, Stephanie Fonda, and Estenda Solutions (Drew Lewis & Richard [RJ] Kedziora) held a focus group to assess the usability of the program. Suggestions to enhance the efficiency of the program were recorded and are being integrated as Study Manager is adapted to new studies. **The Diabetes Institute (DI) Technical Advisor is working with Estenda Solutions, Inc, the software developers of Study Manager, in order to assume primary responsibility for adapting study manager to new studies as they are implemented by the DI at WRAMC.**

Deployment of JVN Telehealth CDMP application into the Department of Defense HealtheForces. Robert Vigersky MD, and Sven-Erik Bursell PhD

Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005. The Diabetes Institute staff is currently developing the process and procedures for use of the CDMP in their clinic and the Usability/Workflow Study has been completed and findings are being used to further refine CDMP as a case management tool (see #2 above). The elimination of HealtheForces and, consequently interfacing to the Armed Forces Health Longitudinal Technology Application or AHLTA (CHCSII) are currently being investigated. A three-stage plan for integration is being modified to be consistent with the Common Development Environment (CDE) being developed by TATRC as a platform for the integration of clinical programs such as CDMP into AHLTA. Currently, The Diabetes Institute is engaged in one study, the **"Integration and Assessment of a Diabetes Assessment Tool Kit in AHLTA" and two additional projects** that are continuing the effort initiated by DATK to integrate additional features of CDMP into AHLTA: (1) **The Evaluation of Multiple Methods of Viewing and Integration of Glucometer Data through Diabetes Mellitus Everywhere (DME), the Patients' Portal in the Comprehensive Diabetes Management Program (CDMP) into AHLTA** and (2) **Bi-Directional Merging of the Comprehensive Diabetes Management Program (CDMP) database with AHLTA CDR via the MHS Common Development Environment (CDE).**

The DATK Study

The DATK consists of a risk stratification algorithm for diabetes-related complications and two questionnaires, the Behavior Assessment Tool (BAT) and the Nutrition Assessment Tool - A (NAT-A). The DATK is intended to help providers quickly screen for diabetes-related psychosocial problems (such as smoking, depression, low adherence to recommended appointments, no control of diet, etc.) and clinical problems (such as increased risk of diabetic retinopathy, nephropathy, etc). The DATK is web-based and can "stand-alone", as can its components.

The protocol reflects the modifications required by the CDE. The implementation of this study will serve as one of the first prototypes for the integration of clinical programs into AHLTA. **A total of 70 subjects are currently enrolled in this study; 53 enrolled in the period of performance for this report.**

The overall aim of the first project, short title, "DME", is to integrate relevant and unique outcomes of the Diabetes Mellitus Everywhere (DME) patient web-based portal into the CDE and evaluate the ease of using DME and accuracy of uploaded data. DME provides patients with a mechanism to upload self-monitored blood glucose (SMBG) data from their homes to their provider for analysis. DME then gives simple statistical and graphical summaries of the SMBG test results as well as electronic diabetes-related information. Enhancing patients' understanding and use of SMBG data together with relevant diabetes education can result in improved glycemic control with a subsequent risk reduction in complications associated with chronically uncontrolled diabetes.

The primary aim of the second project, short title, "Bi-di", is to build a bi-directional interface between the CDMP and the CDE. This interface will provide an evaluation of how effectively a web-base patient care system can completely integrate with AHLTA by providing data from the AHLTA Central Data Repository (CDR) into the web-based CDMP and taking the calculated information and graphs along with externally collected data, and load that data back into AHLTA. The DI and Estenda Solutions, Inc are working closely with TATRC to: (1) Develop a DHIMS acceptable Requirements Document / Initial System Design Document (SDD) that identifies the needs and requirements for integrating the CDMP and AHLTA databases, (2) Develop the prototype of Telemedicine Tele-

Consultation interface within the MHS CDE, (3) Establish a sync-manager process that will, as CPU cycles permit, initiate a process on the site's Local Cache Server (LCS) to grab an XML file generated by the CDMP server and load the AHLTA CDR with the patient's Care Plan, Education Evaluation, Surveys, Personal Biometric Data/Home Monitoring Data (HMBG, BP, Weight), Risk Profile, and JVN non-mydratic retinal Images and Reports, and (4) Enhance the security model, improving the secure link between the application and Web-services server by implementing the X.509 security certificate which is an ITU-T standard for a public key infrastructure (PKI) for single sign-on and Privilege Management Infrastructure (PMI).

The Diabetes Institute and Estenda Solutions, Inc are working extensively with TATRC and the Department of Information Management (DOIM) at WRAMC to gain access to and consequently to meet all the security requirement of that access to the WRAMC network in order to accomplish the aims of both "DME" and "Bi-Di". .

Conclusion

Diabetes mellitus is a significant cause of morbidity and mortality in the United States, and the leading cause of new blindness, chronic kidney disease, and non-traumatic amputation in the working-aged American population. Strategies are in place that, based on solid clinical and scientific evidence, can significantly reduce complications of diabetes through timely treatments and appropriate management. Unfortunately, less than 50% of patients with diabetes obtain appropriate medical care. Additionally, there are nearly 8 million Americans with diabetes who are unaware of their condition.

The Joslin Vision Network is a telemedicine initiative that has the potential to bring the highest quality care to all patients with diabetes. The JVN Telehealth program is a web-based interactive telemedicine application that can systematize the organization of disease and care management, that centralizes the patient in the care process, that can impact the ability of diabetic patients to more effectively manage their diabetes, improve their metabolic control, reduce the level of emotional stress associated with managing diabetes, and reduce the incidence of complications through implementation of the CDMP program.

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Appendix A

The CDMP is a web-based diabetes case management tool developed by a consortium of researchers, physicians, and educators specializing in diabetes and its management. The consortium was drawn from the Joslin Diabetes Center, the Department of Defense [Walter Reed Army Medical Center (WRAMC) and Tripler Army Medical Center (TAMC)], Veterans Health Affairs (Boston Veterans Hospital), and the Indian Health Service (IHS). The overall goal behind the development of the CDMP is to provide an interactive, web-based clinical tool for care managers that improves diabetes care. The CDMP is intended to: provide an automatic system to foster a high level of continuous care and communication among patients, care managers, and physicians; insure that the latest clinical guidelines are used in the care; and focus on *both* clinical and behavioral patient problem areas, rather than just clinical areas, as is usually the case in diabetes care.

The standard clinical care for a patient with diabetes typically follows a pattern similar to that outlined below:

- 1) Patient assessment by review of medical records and lab reports, taking a medical history, and performing a physical examination;
- 2) Assessment of the physical, psychological, and learning status of the patient (via formal or informal interviewing techniques and/or exams);
- 3) Preparation and maintenance of a treatment plan for the patient, with an emphasis on patient self-management;
- 4) Referral of patient needing immediate medical care for non-diabetic problems to his/her primary care provider (PCP) or identification of a PCP for any patient who does not have one;
- 5) Referral of the patient to consultants (e.g. ophthalmology, cardiology, and nephrology) as needed;
- 6) Referral of the patient to diabetes education services, including classes, booklets, and other media;
- 7) Ongoing follow-up and feedback to the patient and treatment providers.

By contrast, the CDMP was designed to contribute to the standard clinical process by:

- 1) Generating three levels of alerts for the care manager or provider, all of which are based on a risk assessment algorithm and American Diabetes Association (ADA) and Diabetes Institute (DI) diabetes management guidelines (see below) in advance of the clinic visit;
- 2) Providing clinical assessment, notification, and communication tools;
- 3) Tracking availability and patient use of educational resources that are site and user specific;
- 4) Summarizing patient knowledge and the impact of educational interventions;
- 5) Providing dynamic care planning which is done with the patient and targets physical wellness, lifestyle self-management, and psychosocial health (including possible patient barriers in these areas);
- 6) Connecting with the health organization's health information system or available electronic data (with provisions for client and medical records privacy).

The CDMP is based on current ADA clinical practice guidelines (CPGs) and those of the Diabetes Institute of the WRHCS. They focus on diabetes clinical

management, lifestyle modification and psychosocial health. In the CDMP case management model, the care manager is the key coordinator between patients and the healthcare team that includes MDs, NPs, educators, sub-specialists, nutritionists, and behavioral clinicians.

The CDMP is designed to be superimposed functionally and integrated into the HealtheForces Integrated Clinical Data Base (ICDB) until it is de-commissioned and then into CHCS II. There is a CDMP server housed in the Department of Information Management, WRAMC.

CDMP generates "alerts" when a patient has experienced a particular health event or when the results from a patient's test exceed a pre-determined clinical threshold. Alerts are presented to the care manager/provider on his/her home page when next s/he logs into ICDB. The alerts are "red" (high risk), "yellow" (medium risk), and "green" (low risk) icons and are based on the CPGs. Selecting the alert icon activates search options specific to the patient; e.g., demographic data, medication list, laboratory results, the event or result that generated the alert, available options for the care plan, and follow-up actions. These are displayed with a pull-down menu from which the care manager/provider can select various actions to be taken in response to the alert.

The CDMP also provides an overall clinical risk stratification of each patient. The stratification indicates whether and how the patient is above or below established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. Together with the care manager's/provider's knowledge of his/her patient, the risk stratification allows the care manager/provider to devise an individualized care plan that includes recommendations regarding the patient's goals, lifestyle, monitoring needs, and areas requiring further education. The risk stratification indicates whether patients are "high risk", "moderate risk", or "low risk" based on the Joslin Diabetes Center Clinical Guidelines for Adults with Diabetes.

CDMP has a section on patient education. This section lists the educational tools available at a particular site (e.g., videos, books, classes) and provides an evaluation of how advanced each tool is. The care manager and/or the diabetes educator can then assign educational tools, track each patient's use of the tools, and thus obtain a summary of a patient's knowledge and the impact of the educational intervention.

The CDMP contains other features intended to assist the care manager/provider in the organization of his/her caseload. For example, the CDMP home page shows the care manager's/provider's daily reminders. The reminders show the patient's name, the type of reminder needed (e.g., clinical assessment, modification of the care plan, etc.), and pertinent details regarding the reminder such as type of action needed. The CDMP home page also shows each day's upcoming appointments. Further, there is a scheduler within the CDMP that helps care managers to schedule routine appointments. Finally, the CDMP provides the care manager/provider easy access to complete, and/or up-to-date paperless records of each patient in his/her caseload. For each patient, these records include a history of his/her behavioral assessment, a photograph, demographics and vital signs, medication usage, record of laboratory results, health care procedures the patient has had, diagnoses, patient admission history, education history, and the results (if performed) of the non-dilated retinal examination using the Joslin Vision Network digital, stereo non-mydiatic cameras. The Joslin Vision Network is already located in 4 sites in

the Walter Reed Health Care System (WRAMC, Kimbrough Ambulatory Care Center, Dewitt Army Community Hospital, and Fairfax Family Health Clinic), so this information will be included in the CDMP at the Diabetes Institute when it is deployed.

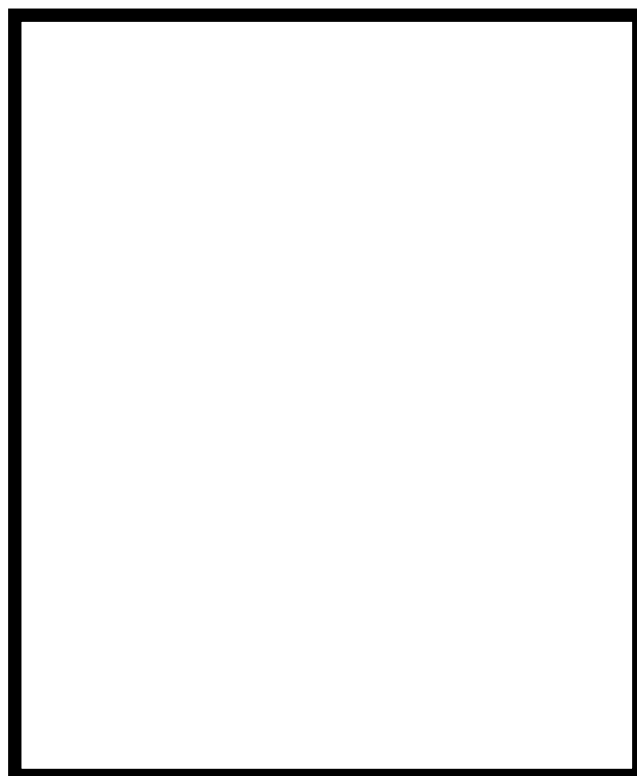
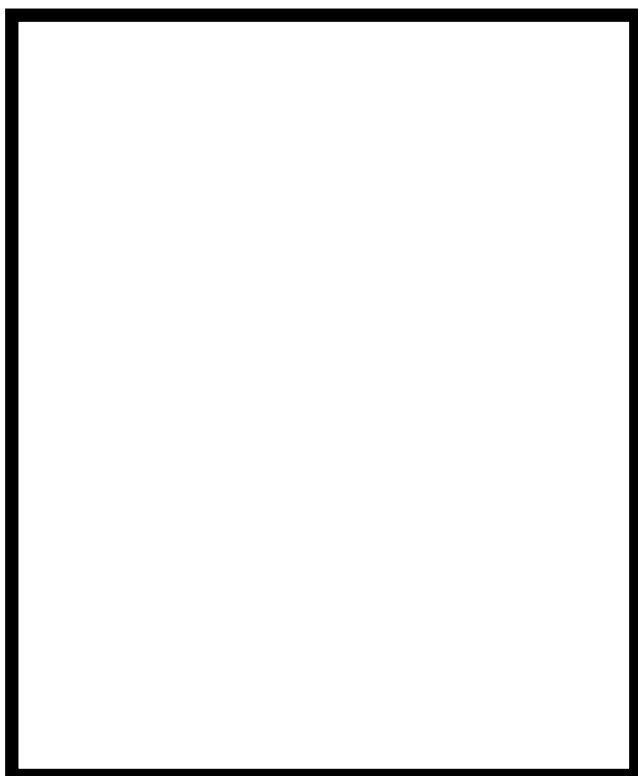
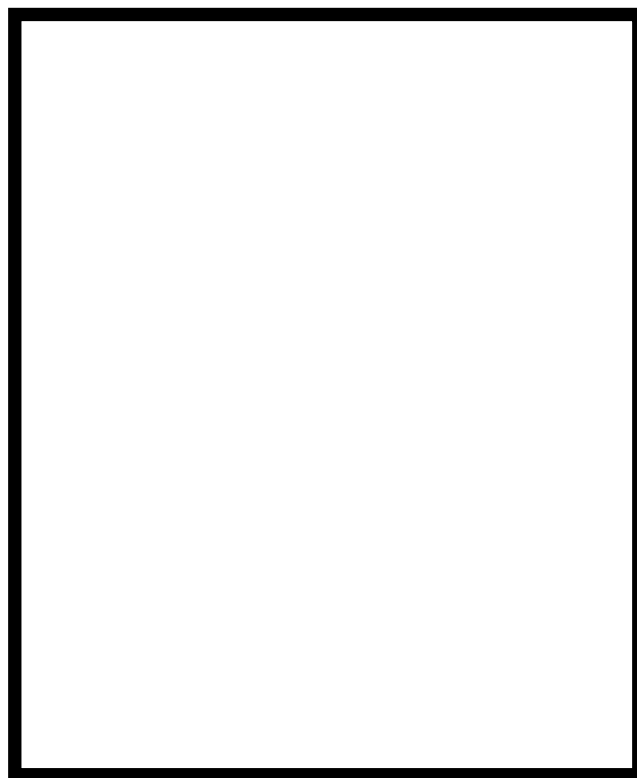
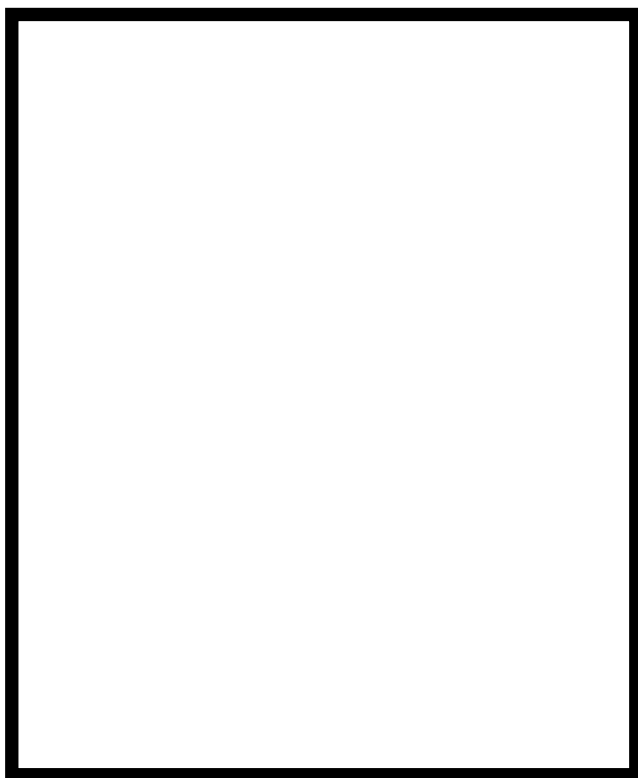
Appendix B

SECTION A. CLOCK DRAWING EXERCISE

Please read and do the following carefully:

- *In the blue box on the next page:*
- *Draw a picture of a clock*
- *Put in all the numbers*
- *Set the time to ten after eleven*

Hand this sheet back and go to the next page



SECTION B. BACKGROUND INFORMATION

1. **What is your date of birth?**

		/			/				
<i>M</i>	<i>M</i>		<i>D</i>	<i>D</i>		<i>Y</i>	<i>Y</i>	<i>Y</i>	<i>Y</i>

2. **Are you male or female?**

<input type="radio"/>	<i>Male</i>
<input type="radio"/>	<i>Female</i>

3. **Do you consider yourself to be Spanish, Hispanic, or Latino (Latina)?**

<input type="radio"/>	<i>Yes</i>
<input type="radio"/>	<i>No</i>

4. **What race do you consider yourself to be? Select one or more of the following:**

	Yes	No
--	------------	-----------

a. *American Indian or Alaska Native**O**O*b. *Asian**O**O*c. *Black or African American**O**O*d. *Native Hawaiian or other Pacific Islander**O**O*e. *White or Caucasian**O**O*f. *OTHER**O**O*f1. *SPECIFY*5. **What is the highest grade or level of school you have completed or the highest degree you have received?**

- | | |
|----------|--|
| <i>O</i> | <i>Less than high school</i> |
| <i>O</i> | <i>High school diploma (including GED)</i> |
| <i>O</i> | <i>Some college</i> |
| <i>O</i> | <i>College degree (including Associate's or Bachelor's Degree)</i> |

- ☐ Some graduate school
- ☐ Graduate or professional degree (including MA; MS; Master's, MBA, Law and MD, PhD)

6. **How many people, including yourself, are supported on your household's income?**

--	--

PEOPLE

7. **Including income from wages, salaries, Social Security or retirement benefits, help from relatives, veteran's benefits, real estate, investments, and other sources, about how much was your total household income in the last 12 months?**

- ☐ Less than \$5,000
- ☐ \$5,000 - \$9,999
- ☐ \$10,000 - \$19,999
- ☐ \$20,000 - \$29,999
- ☐ \$30,000 - \$39,999
- ☐ \$40,000 - \$49,999
- ☐ \$50,000 - \$59,999
- ☐ \$60,000 - \$69,999
- ☐ \$70,000 - \$79,999
- ☐ \$80,000 - \$89,999
- ☐ \$90,000 - \$99,999
- ☐ \$100,000 or more
- ☐ Don't know

8. **Are you currently covered by public (e.g., Medicare, Medicaid) or private (e.g., through your or your spouses' job, etc.) health insurance?**

- ☐ Yes
- ☐ No

SECTION C. BEHAVIORAL ASSESSMENT TOOL

Bat Study Questionnaire	<i>STUDY PARTICIPANT ID</i>							
	<i>DATE</i>							
			/			/		
	<i>M</i>	<i>M</i>		<i>D</i>	<i>D</i>		<i>Y</i>	<i>Y</i>

1. *Is English your native language?*

- ☐ No
☐ Yes

Go to next question
Skip to question # 3

2. *When you learn something new, does it help to hear it in your native language?*

- ☐ Yes
☐ No
☐ *Don't know or not sure*

3. *Would you like someone who speaks your native language to help you complete this survey?*

- ☐ Yes
☐ No
☐ *Don't know or not sure*

4. *Do you have problems reading and understanding written materials?*

- ☐ Yes
☐ No
☐ *Don't know or not sure*

Go to next question
Skip to question #6

5. *Would you like someone to read the survey questions to you?*

- ☐ Yes
☐ No

- ☐ *Don't know or not sure*

Diabetes History

6. *When were you first told you have diabetes?*
- ☐ *I was just diagnosed within the last 12 months*
 - ☐ *1 - 5 years ago*
 - ☐ *6 - 10 years ago*
 - ☐ *More than 10 years ago*
 - ☐ *Don't know or not sure*

Nutrition

7. *On a typical day, how many servings of fruits and vegetables do you eat?*
- ☐ *None*
 - ☐ *1 - 5 servings*
 - ☐ *6 – 10 servings*
 - ☐ *More than 10 servings*
 - ☐ *Don't know or not sure*
8. *During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?*
- ☐ *0 days*
 - ☐ *1 - 5 days a week*
 - ☐ *6 - 7 days a week*
 - ☐ *Don't know or not sure*
9. *How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?*
- ☐ *0 times*
 - ☐ *1 - 2 times*
 - ☐ *3 - 5 times*
 - ☐ *6 or more times*
 - ☐ *Don't know or not sure*

Physical Activity

10. *How would you describe your physical activity level?*
- ☐ *Sedentary or lightly active (Mostly sitting or lying down, e.g., TV, reading; Sitting or standing most of the day, e.g., desk work, teaching, white collar work, light housework)*
 - ☐ *Moderately active (Standing or walking, moving most of the day, e.g., heavy housework, brisk walking, gardening)*
 - ☐ *Very active (Moving strenuously, e.g., aerobics, biking, hiking, running, climbing stairs, mowing lawn, manual labor)*
 - ☐ *Don't know or not sure*
11. *In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more?*
- ☐ *0 times*
 - ☐ *1 - 3 times*
 - ☐ *4 - 6 times*
 - ☐ *More than 6 times*
 - ☐ *Don't know or not sure*

Checking Blood Sugars

12. *How often do you check your blood sugar?*
- ☐ *Never*
 - ☐ *Less than once a week*
 - ☐ *1 - 5 days a week*
 - ☐ *About once a day*
 - ☐ *Twice a day or more*
 - ☐ *Don't know or not sure*

Medications

13. *In the last 7 days, how often did you miss taking your diabetes pills or insulin?*
- ☐ *One time a week*

- ☐ *2 - 4 times a week*
- ☐ *Most days*
- ☐ *Everyday*

Mood

14. During the past month have you often been bothered by feeling down, depressed, or hopeless?
- ☐ *Yes*
 - ☐ *No*
 - ☐ *Don't know or not sure*

15. *During the past month have you often had little interest or pleasure in doing things?*

- ☐ Yes
- ☐ No
- ☐ *Don't know or not sure*

Alcohol

16. *Do you drink alcohol?*

- ☐ Yes
- ☐ No

Go to next question
Skip to question #18

17. *Are you concerned about your drinking?*

- ☐ Yes
- ☐ No

Smoking

18. *Do you smoke cigarettes, cigars, a pipe, or chew tobacco?*

- ☐ Yes
- ☐ No
- ☐ *No, but I quit within the last 6 months*

Your health

19. *In general, would you say your health is:*

- ☐ *Excellent*
- ☐ *Very Good*
- ☐ *Good*
- ☐ *Fair*
- ☐ *Poor*

20. *Have you been examined by an eye doctor in the last 12 months?*

- ☐ Yes
- ☐ No
- ☐ *Don't know or not sure*

21. *How often do you check your feet for sores, cuts, or bruises?*
- ☐ *Never*
 - ☐ *Once a month*
 - ☐ *Every couple of weeks*
 - ☐ *At least once a week*
 - ☐ *Every day*
 - ☐ *Don't know or not sure*
22. *Have your feet been examined by a doctor in the last 12 months?*
- ☐ *Yes*
 - ☐ *No*
 - ☐ *Don't know or not sure*
23. *Do you use other healing methods or remedies in addition to those prescribed for you?*
- ☐ *Yes*
 - ☐ *No*
 - ☐ *Don't know or not sure*

Support from Family and Friends

24. *Do you have family and friends you can ask for help?*
- ☐ *Yes*
 - ☐ *No*
 - ☐ *Don't know or not sure*
25. *Do your family and friends live in your house or nearby?*
- ☐ *Yes*
 - ☐ *No*
 - ☐ *Don't know or not sure*

Go to next question

Skip to question #26

Skip to question #26

26. *Do you agree with the following statement? My family and friends support me by encouraging me to do things to improve my health.*
- ☐ Strongly agree
 - ☐ Agree
 - ☐ Neither agree nor disagree
 - ☐ Disagree
 - ☐ Strongly disagree

Coming to the clinic

27. *Do you have problems getting to the clinic?*
- ☐ Yes
 - ☐ No
28. *How long does it usually take you to get to the clinic?*
- ☐ Less than 30 minutes
 - ☐ 30 minutes to an hour
 - ☐ More than an hour
 - ☐ Don't know or not sure
29. *How do you usually get to the clinic?*
- ☐ My family or a friend drives me
 - ☐ I drive myself
 - ☐ I ride a van or bus or train
 - ☐ I walk or ride a bicycle
 - ☐ Other

Education

30. *How do you like to learn about new things?*

	Yes	No
a. <i>Watching slides or videos</i>	<input type="radio"/>	<input type="radio"/>

b. Reading	<input type="radio"/>	<input type="radio"/>
c. Others showing me how	<input type="radio"/>	<input type="radio"/>
d. Discussions	<input type="radio"/>	<input type="radio"/>
e. Listening to others	<input type="radio"/>	<input type="radio"/>
f. Using computers	<input type="radio"/>	<input type="radio"/>
g. In a class	<input type="radio"/>	<input type="radio"/>
h. Other ways	<input type="radio"/>	<input type="radio"/>

31. How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?

- ☐ A lot
☐ Some
☐ None
☐ *Don't know or not sure*

32. Would you like to learn more about taking care of your diabetes?

- ☐ Yes
☐ No
☐ *Don't know or not sure*

More About You

33. Which **BEST** describes you? (Choose only one answer.)

- ☐ Employed full-time
☐ Employed part-time
☐ Disabled
☐ Retired
☐ Student
☐ Looking for work
☐ Other

34. Do you have any vision problems?

- ☐ Yes
☐ No
☐ *Don't know or not sure*

35. Do you have any hearing problems?

- ☐ Yes
- ☐ No
- ☐ Don't know or not sure

36. Do you have any problems walking?

- ☐ Yes
- ☐ No
- ☐ Don't know or not sure

37. Do you have problems remembering things?

- ☐ Yes
- ☐ No
- ☐ Don't know or not sure

38. Do you have any money issues that affect your ability to take care of any of the following items?

	Yes	No
a. Medication	<input type="radio"/>	<input type="radio"/>
b. Food	<input type="radio"/>	<input type="radio"/>
c. Transportation	<input type="radio"/>	<input type="radio"/>
d. Self-monitoring supplies	<input type="radio"/>	<input type="radio"/>

39. Do you have any concerns about your diabetes that we have not covered today? If you check yes, someone from the staff will talk to you about them. (NOTE: QUESTION WILL NOT BE ASKED FOR THIS STUDY)

- ☐ Yes
- ☐ No
- ☐ Don't know or not sure

SECTION D. FINAL QUESTION

1. *Did you complete these questions with help from another person?*
- ☐ *Yes*
 - ☐ *No*
 - ☐ *Don't know or not sure*

Appendix C.1 Behavioral Assessment Tool Questions

Note that the format of the questionnaire will be different in the PureEdge Forms. These forms are not completed yet, so we cannot show them here.

Name:	Last 4 of your SSN:
1. Is English your native language?	
2. When you learn something new, does it help to hear it in your native language?	
3. Would you like someone who speaks your native language to help you complete this survey?	
4. Do you have problems reading and understanding written materials?	
5. Would you like someone to read the survey questions to you?	
Diabetes History	
6. When were you first told you have diabetes?	
Nutrition	
7. On a typical day, how many servings of fruit and/or vegetables do you eat?	
8. During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?	
9. How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?	
Physical Activity	
10. How would you describe your physical activity level?	
11. In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more (e.g., heavy housework, brisk walking, gardening, aerobics, biking, hiking, running, climbing stairs, mowing the lawn, manual labor)?	
Checking Blood Sugars	
12. How often do you check your blood sugar?	
Medications	
13. In the last 7 days, how often did you miss taking your diabetes pills or insulin?	
Mood	
14. During the past month, have you often been bothered by feeling down, depressed, or hopeless?	
15. During the past month, have you often had little interest or pleasure in doing things?	
Alcohol	
16. Do you drink alcohol?	
17. Are you concerned about your drinking?	
Smoking	
18. Do you smoke cigarettes, cigars, a pipe, or chew tobacco?	
Your health	
19. In general, would you say your health is:	
20. Have you been examined by an eye doctor in the last 12 months?	
21. How often do you check your feet for sores, cuts, or bruises?	
22. Have your feet been examined by a doctor in the last 12 months?	
23. Do you use other healing methods or remedies in addition to those prescribed for you?	
Support from friends and family	
24. Do you have family and friends you can ask for help?	
25. Do your friends and family live in your house or nearby?	
26. Do you agree with the following statement?	
My family and friends support me by encouraging me to do things to improve my health.	

<i>Coming to the clinic</i>
27. Do you have problems getting to the clinic?
28. How long does it usually take you to get to the clinic?
29. How do you usually get to clinic?
<i>Education</i>
30. How do you like to learn about new things?
31. How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?
32. Would you like to learn more about taking care of your diabetes?
<i>More about you</i>
33. Which best describes you? (question pertains to employment status)
34. Do you have any vision problems?
35. Do you have any hearing problems?
36. Do you have any problems walking?
37. Do you have problems remembering things?
38. Do you have any money issues that affect your ability to take care of any of the following items: medication, food, transportation, and self-monitoring supplies?
39. Do you have any concerns about your diabetes that we have not covered today? If you check yes, someone from the staff will talk to you about them.

Appendix C.2
Nutritional Assessment Tool -- A

Note that the format of the questionnaire will be different in the PureEdge Forms. These forms are not completed yet, so we cannot show them here.

Name:

Last 4 of your SSN:

Question	Answer
Have you seen a Dietitian (or Nutritionist) for your diabetes within the last 12 months?	Yes / No / I don't know
Do you have any religious, cultural, or personal beliefs that should be part of your diabetes care?	Yes / No
Do you have any food allergies or intolerances?	Yes / No
Do you take Vitamins, Herbs, minerals or any other supplements?	Yes / No
Who does most of the food shopping for the home?	1. Self only 2. Spouse or Significant Other only 3. Self and another person 4. Community/Home Health Worker only 5. Other
Who prepares most of the meals at home?	1. Self only 2. Spouse or Significant Other only 3. Self and another person 4. Community/Home Health Worker only 5. Other
How many times per week do you eat your main or big meal away from home (e.g. takeout, café/restaurant, friend's or family's home, Elder Center, etc.)?	1. 0-1 times per week 2. 2-3 times per week 3. More than 3 times per week
How satisfied are you with how you are managing your eating plan?	1. Not at all satisfied 2. Somewhat satisfied 3. Very satisfied 4. Don't have an eating plan
Does your mood affect your eating habits?	Yes / No
If you have ever tried to make changes in what you eat, how successful were you?	1. Not at all successful 2. Somewhat successful 3. Very successful 4. Never tried to make changes
Would you like information about any of these topics? Check boxes:	1. Avoiding Hypoglycemia 2. Avoiding Hyperglycemia 3. Meal Planning for Diabetes 4. Choosing Healthy Snacks 5. Eating Away From Home 6. Managing Diabetes during Holidays and Celebrations 7. Grocery Shopping and Food Labels 8. Modifying Recipes 9. Losing Weight 10. Physical Activity 11. Eating for a Healthy Heart 12. Eating to Keep Your Kidneys Healthy

Appendix C.3

Risk Stratification Algorithm and Report for Fictitious Patient

Comprehensive Diabetes Management Program

[Home](#) | [My HM Data](#) | [Status Center](#) | [Private Msgs](#) | [Search](#) | [H](#)
[JVN](#) | [Studies](#) | [Add Patient](#) | [User Pref](#) | [Admin](#) | [Log Out](#)

Patient Menu

Patient Info

Snapshot

Alerts/Reminders

Clinical

Home Monitoring

Risk Profile

Limited

New Detailed

Detailed History

Education

Survey History

JVN Report

Image Catalog

Care Plan

DME

Add/Edit Patient Data

Private Msgs

Encounter

Survey Request

open all | close all

New Detailed Risk Stratification Report for: Robert Salvo

Reset

Clear

Create

A1C

Recent Readings:

1. A1C (Most Recent)

Date: 11/15/2006

Result: 6.8

2. A1C

Date: 11/08/2006

Result: 9g

Interventions

Medication Adjustment

Meal Plan Adjustment

Education Session

Cardiovascular Health

Risk Factors

Family Hx of CAD

Obesity

Vascular Bypass Surgery

Has Been Diagnosed With

Large Vessel Disease/Atherosclerosis

CAD

Angina

MI

CABG/PTCA

Claudication

Orthostatic Hypotension

Stroke/TIA

PVD

Interventions

ASA

ASA Contraindicated

Lipids

Total Cholesterol:

Date:

Result:

HDL:

Date: 02/21/2006

Result: 38

LDL:

Date: 02/21/2006

Result: 127

Triglycerides:

Date: 02/21/2006

Result: 163

Interventions

